Use of MEDDRA in AERS

Medical Dictionary for Regulatory Activities

(Medical Dictionary for Drug Regulatory Affairs)

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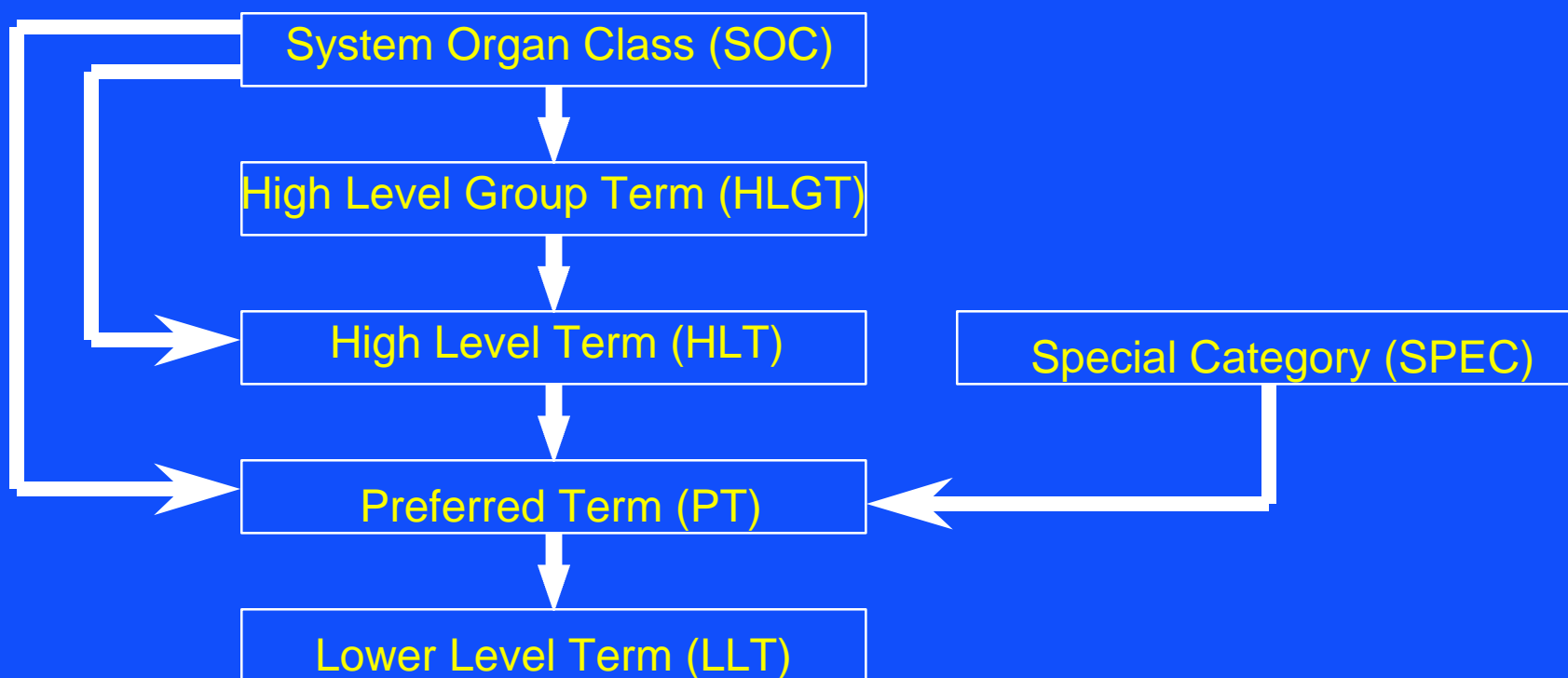Chair, MEDDRA Project Advisory

Group for AERS

ICH PMS Initiatives

- *M1 Nomenclature (MEDDRA)*
- M2 Electronic Transmission Vehicle
- E2A Expedited ADR
- E2B Electronic Data Format
- E2C Periodic- PSUR

Terminologies Included in MEDDRA

- MCA Medical Terminology
- COSTART (5th ed)
- WHOART (95:3)
- J-ART   (1993)
- ICD-9
- ICD-9-CM   (4th Revision)
- HARTS   (Release 2.2)

MEDDRA STRUCTURAL HIERARCHY

System Organ Class (SOC)

High Level Group Term (HLGT)

High Level Term (HLT)

Special Category (SPEC)

Preferred Term (PT)

Lower Level Term (LLT)

MEDDRA
Numbers of Terms per Hierarchial Level

	v1.5	*v1.9*
• SOC	26	26
• HLGT	88	338
• HLT	653	1667
• PT	8658	11107
• LLT	35335	46171

COSTART   1199 Terms

26 SYSTEM ORGAN CLASSES (SOC) OF MEDDRA

Investigations
Cardiac disorders
Congenital and familial/genetic disorders
Disorders of blood & the lymphatic system
Neurological disorders
Disorders of the eye
Disorders of the ear & labyrinth
Respiratory, thoracic & mediastinal disorders
Gastrointestinal disorders
Renal & urinary disorders
Skin & subcutaneous tissue disorders
Musculoskeletal, connective tissue & bone disorders
Endocrine disorders
Disorders of metabolism & nutrition
Infections & infestations
Injury & poisoning
Benign & malignant neoplasms (including cysts and polyps)
Surgical & medical procedures
Vascular disorders
General disorders
Pregnancy, puerperium & perinatal conditions
Social circumstances
Disorders of the immune system
Hepato-biliary disorders
Disorders of the reproductive system and breast
Psychiatric disorders

System Organ Class Reviews

Performed by the FDA

COSTART to MEDDRA Mapping Validation

- Migration of Spontaneous Reporting System (SRS) data into AERS
- COSTART: one to many relationships

MEDDRA
"Production" Version

Use in FDA AERS implementation

Current Availability of MEDDRA

- Manufacturers Participating in Electronic Submission Phase III Pilot Program   *MEDDRA v2.0*

- FDA Contact for Signup:
  Ralph Lillie 301-827-3222

Current Availability of MEDDRA

- Manufacturers NOT Participating in Electronic Submission Phase III Pilot Program   *MEDDRA v1.5*

- Contact:

  Chris LeGrand, BDM International, Inc.

  (703) 848-6331

MEDDRA v2.0

- "official", "licensed" version of MEDDRA

- general availability when international maintenance organization (IMO) is in place

FDA Use of MEDDRA

Replacement of COSTART terminology

- Coding of Adverse Events in AERS
  - no limit to number of event terms
- Coding of Indications

MEDDRA Coding Principles

- General principles developed which would apply to any terminology
- Additional coding principles being developed specific to MEDDRA as coding process begins

MEDDRA Searching Guide

- General Principles for Searching
- COSTART to MEDDRA Mapping
- Cross Reference for COSTART grouping terms (midlevel) to MEDDRA grouping terms (HLT, HLGT, SOC)

  Work in Progress !

Designated Medical Events (DMEs) (examples)

- Agranulocytosis
- Aplastic anaemia
- Respiratory failure
- Torsade de pointes
- Malignant Hypertension

- Convulsion
- Epidermal necrolysis
- Hepatic failure
- Anaphylactic Shock

ELECTRONIC ADR SUBMISSION

- Implements ICH - M1, M2, E2B

- *Require International Medical Terminology (MEDDRA)*

- Require Electronic Submissions of <u>ALL</u> Manufacturer Reports, *Precoded*, using E2B format via ESTRI specifications in ICH-M2

Phase III Pilot: Acceptance of Uncoded Data

FDA Use of AutoCode
an assist tool

- Coding of Adverse Event Reports

   (event + indication)

- Browsing the MEDDRA terminology
   – Search Strategy Development

- Quality Control - Manufacturer's Electronic Submissions

   REQUIRES QUALIFIED HUMAN CODER !

QUESTIONS